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The Results of the Total Hip Arthroplasty Using 3D Printing Technology

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Objectives: To study the value of 3D printing of custom THA femoral prostheses with conventional femoral prostheses in total hip arthroplasty for severe hip deformity. **Methods:** Total hip arthroplasty was used in the treatment of 107 severe hip joint deformity cases from June 2018 to June 2019. Fifty-six patients received conventional hip replacement stems and 51 patients received a custom 3D printed hip replacement stem designed to address their proximal deformity and leg length discrepancy. The operation time, intraoperative blood loss, postoperative weight-bearing time, Harris score before and after the operation, complications after surgery and the main angle measurement of compared to their contralateral hip were evaluated to determine the short-term efficacy of 3D printed total hip replacement femoral prosthesis compared to the common total hip replacement femoral prosthesis. **Results:** A total of 107 patients were followed up for an average of 12 months. The use of 3D printing technology in the preoperative design and custom prosthesis fabrication was associated with shortened operation time, less intraoperative blood loss, quicker time to postoperative full weight-bearing, and improved the Harris score in 1 year after the operation compared to conventional total hip replacement stem ($p<.05$). Our results revealed that there was a significant reduction in the femoral anteversion with a value of 13.06 ± 1.93 degrees (mean $\pm$ SD) in the custom prosthesis group compared to the conventional hip replacement group. However, there was no significant difference in neck-shaft angle, acetabular angle, and Sharp angle between both groups ($p>.05$). **Conclusion:** 3D printing technology created a virtual and realistic simulation, and personalized operation plan for patients with severe hip deformity, which was helpful for surgical treatment. The anatomical characteristics of patients with complex deformities were better addressed using the 3D printed femoral component and resulting in better patient outcomes and provided a new option for surgeons to manage these difficult cases.

Keywords: 3D printing technology; Total hip arthroplasty; Developmental dysplasia of the hip; Femoral neck anteversion

Introduction

The World Health Organization reported that an estimated 10 million incident tuberculosis (TB) cases and 1.5 million TB deaths occurred in 2018 worldwide [1]. Among the extrapulmonary forms of TB, osteoarticular TB is still prevalent and represents approximately 15% of extrapulmonary TB [2]. In remote areas like in Inner Mongolia in Northern China, the socioeconomic constraints, such as the non-optimal medical care system and the economic status of the population, often result in delayed presentation for treatment of osteoarticular TB [3]. Hip TB, the second most common form of osteoarticular TB, is usually found in children and it results in a severe hip deformity in adult life, by which time the joint no longer can be preserved [4]. Due to the delayed diagnosis, not only hip TB but also developmental dysplasia of the hip (developmental hip dysplasia) is also common in Inner Mongolia, which in turn results in the high incidence of Crowe III or IV type of hip dysplasia [5]. In Crowe IV grade, there are fixed deformities of the hip and pathologic dislocation of the hip as well as altered anatomy of the acetabulum and proximal femur [6].

Total hip arthroplasty (THA) is one of the most effective orthopedic procedures for treating patients with hip deformities due to resolved deep infection and developmental hip dysplasia, and it has been used in China since the late 1980s [7]. THA offers reliable relief of pain, correction of leg length inequality, and significant improvement in joint mobility as well as the restoration of a person's ability to perform functional activities [7]. However, in Crowe grade IV developmental hip dysplasia, THA is a challenging surgery due to the need for optimization of the shape of the femoral implant to the abnormal shape of the proximal femur. Specifically, the implant needs to enable accurate positioning of the femoral component in the narrow and excessively anteverted proximal femur with a shortened femoral neck [6]. Conventional THA components are not ideally adaptable for these cases, and this leads to complications such as intraoperative fracture and frequent implant positioning compromises that adversely affect the patient's outcome [8,9]. Therefore, numerous attempts have been made in Inner Mongolian hospitals in recent years to perform THA for severe hip deformities using a femoral component made using a 3D printing technique [10]. Obtaining preoperative MRI and CT images of the patient's hip allows the surgeon to validate the optimal design and position of the femoral prosthesis and reduce surgical complications [11]. Moreover, 3D printing of patient-specific joint model can be a useful tool to explain to patients the details of the surgical procedure, including the challenges of accurately positioning the cup in the shallow acetabulum with deficient anterior wall and thick medial wall and implanting the femoral component in the excessively anteverted proximal femur with a narrow canal.

The extent of developmental hip dysplasia has been traditionally quantified using the 2D single plane measurements such as the center-edge angle of Wiberg (CEA), femoral neck anteversion, as well as the acetabular index of the weight-bearing zone [12]. Among these, the femoral neck anteversion has important implications in selecting the femoral THA component and can be measured by directly on cadaveric bones, or by using X-ray or 2D/3D CT techniques [13]. Using these same imaging modalities, the thickness of the typically thin anterior acetabular wall, and thickness of the typically thick medial wall of the acetabulum can be determined using CT and the overall acetabular morphology can be studied using 3D-CT reconstructed images [14]. On the other hand, MRI can provide exquisite soft tissue anatomy visualization compared with other techniques and has the benefit of no radiation exposure [15]. Tomczak et al. conducted a study to establish the precise anatomic measurement of femoral neck anteversion using MRI and found that the femoral anteversion was more reliably and reproducibly measured using MRI compared to CT in children and adults [16].

Because of the challenges we have experienced using conventional THA components in developmental hip dysplasia cases with abnormal bony morphology, we sought to study the benefits of using 3D printing technology to create custom femoral THA implants and to compare the results of patients receiving these implants to those who received conventional off-the-shelf femoral components in the same patient population.

Materials and Methods

In this study, 107 patients diagnosed with severe hip deformity from June 2018 to June 2019 were included in our study performed the People's Hospital Affiliated with Inner Mongolia Medical University. Their mean age was 62.7 ± 9.08 years, and 49.5% were male. Of the 107 cases followed for 12 months, 12 were excluded due to incomplete data or were lost to follow-up. Bilateral hip TB or developmental hip dysplasia cases were infrequent enough that they were excluded from the study. Additionally, 2 cases were excluded because of hip pain during scanning, or refusal to be examined or to have a CT scan because of fear of radiation exposure.

The cases were divided into a group of 56 patients who underwent THA using an off-the-shelf conventional femoral THA implant and 51 who received a custom 3D printed femoral prosthesis. Standard total hip replacement acetabular components were used in both conventional and 3D printed femoral implant cases. The shortterm efficacy of the custom femoral implants was compared to the off-the-shelf standard implant, to evaluate the newer method aimed at improving fit, fill, and anteversion outcomes.

Including criteria were as follows: 1) Kellgren - Lawrence Stage III-IV osteoarthrosis, 2) limited range of motion in the hip joint, hip dysplasia due to either developmental dysplasia or TB resulting in significant acetabular deformity and proximal subluxation of the femoral head greater than 50% of the normal contralateral femoral head.

Exclusion criteria were as follows: 1) patients with proximal displacement less than 50% of the normal femoral head or 10% of the pelvis (Crowe I), 2) patients with active hip TB infection or with other pathological conditions such as current infection, high blood pressure, hypertension as well as diabetes.

3D Printing Production Process

To visualize the bony anatomy at the time of surgery and 3D plastic models of the proximal femur, and hemipelvis were printed using an Objet24™ 3D Printer (Stratasys, Eden Prairie, MN, USA). For patients receiving a custom femoral implant, a prototype of the custom THA femoral component was printed using plastic, and the design modified if needed.

The CT scans were performed on a Siemens CT (128 MDCT), (Somatom Definition Flash) 1.5T MRI (Siemens Corp., Berlin, Germany), with a thickness of 0.625 mm, along the long axis of the body [17]. The tube current was 200 mm and the voltage 120 kV. The pixel resolution, window width, and position of the CT image were 512 x 512, 1,800, and 600, respectively. The DICOM format images were saved in a Toshiba and Siemens CT working station (version 10.0; Siemens Corp.) and subsequently exported into the JPG format. ACDSee® (version 15.0, ACDSee, Inc., Bellevue, WA, USA) photo editing software was then used to convert the images into the BMP format, which could be read by the Mimics software (version 15.0; Materialise, Leuven, Belgium) [17]. The Mimics 15.0 program was used to convert CT data, and the 3D stereolithography files. The magnetic coil of the 3D printing machine was operated to control the high-energy electron beam to direct the deposit of the metal powder in the working chamber of the equipment. Molten titanium alloy powder was deposited onto using the digital information to form the linear and planar metal layer-by-layer until the entire femoral component was completed after which its trunnion was finished [17].

Clinical Evaluation

The operative time, intraoperative blood loss, Harris score before and after the operation, complications associated with the surgery, and the difference in leg length compared to the contralateral leg were evaluated for every patient. All patients were instructed to be weight-bearing as tolerated after surgery, and the number of days to achieve full weight-bearing was recorded. Every patient was evaluated for postoperative infection and loosening. Post-op CT images were used to assess the fit and fill of the prosthesis, as well as the femoral neck anteversion, neck-shaft, as well as the acetabular angle and sharp angles.

Statistical Analysis

An independent T-test was used to determine the statistical significance between the two groups. Fisher's Exact Test was used for assessing differences in the distribution of categorical variables between two or more independent groups. Statistical analysis was done in Stata 12.1 For all analyses, $p<.05$ was considered statistically significant.

Ethical Statement

Ethical approval of Inner Mongolian University of Nationalities ethics committee was taken (N0 YKD 20-18095).

Results

A total of 107 cases of severe hip deformity caused by either hip TB or developmental hip dysplasia were included in the study. There were 53 males and 54 females, aged from 40.4 to 85.0 years, with an average of 63.1 years (Table 1). There were 23 cases of childhood hip TB, including 5 cases of bone TB and 18 cases of intraarticular hip TB. The 51 cases of developmental hip dysplasia included 5 cases of Crowe type II, 36 cases of Crowe type III, and 10 cases of Crowe type IV (15 cases of Hartofilakidis type B, and 36 cases of Hartofilakidis type C).

Fifty-six patients underwent hip replacement with a conventional femoral component, and 51 underwent hip replacement with 3D printed femoral component. Both groups were followed-up for 12 months. More of the patients in the custom femoral group were full weight-bearing day 1 postoperatively compared to 3 days for the conventional hip replacement group (3.1 vs. 1.5, p = .001). Moreover, the postoperative Harris hip scores for pain in the 3D printing group were higher than the conventional hip replacement group (93.3 ± 2.7 vs. 81.2 ± 2.8, p = .001), indicating that the hip function of the patients of the 3D group was better. Furthermore, the custom femoral prostheses were better positioned and had lower rates of loosening (2 vs. 3.6% p = .041) and dislocating (2 vs. 3.6%, p = .018) compared to the conventional hip joint replacement group. The operative time was much less for patient receiving the custom femoral component (39.9 ± 10.3 vs. 63.7 ± 10.3 min, p = .001) resulting in less blood loss (525.3 ± 13.4 vs. 550.2 ± 11.2 mL, p=. 001) and fell just short of having fewer infections (2 vs. 5.4%, p = .053). Moreover, there was a slight but significant difference in femoral anteversion angle in the 3D group compared to the conventional femoral components (13.06 ± 1.93 vs. 12.02 ± 3.40, p = .05), while the neck-shaft angle, and acetabular or sharp angles did not differ from the contralateral side (Tables 2, 3 and 4).

Discussion

In most cases, severe hip deformity can seriously affect the quality of life and leads to worsened mental health. The causes of hip deformity at an early age include delayed or neglected presentation of developmental dysplasia, avascular necrosis of the femoral head, infection, enthesopathy, as well as arthritis

Table 1. General characteristics of the study population

Variables	Conventional hip replacement (n = 56)	3D printing hip replacement (n = 51)	P-value
	(mean ± SD)	(mean ± SD)	
Age	64.20 ± 8.73	61.96 ± 9.76	.004
Gender			
Male	27 (48.2 %)	26 (51.0 %)	.775
Female	29 (51.8 %)	25 (49.0 %)	

Table 2. Case categories of the study population

Variables	Conventional hip replacement (n = 56)	3D printing hip replacement (n = 51)	P-value
Case category	N (%)	N (%)	
Tuberculosis	30 (53.6 %)	27 (52.9 %)	.948
Developmental hip dysplasia	26 (46.4 %)	24 (45.1 %)	
Tuberculosis			
Bone	13 (43.3 %)	9 (33.3 %)	.081
Joint	17 (56.6 %)	18 (66.6 %)	
Developmental hip dysplasia			
Grow II	7 (26.9 %)	5 (20.8 %)	.125
Grow III	10 (38.5 %)	8 (33.3 %)	
Grow IV	9 (34.6 %)	11 (45.8 %)	
Follow-up time (months)	12	12	
Developmental hip dysplasia = Developmental dysplasia of the hip			

Table 3. Clinical variables in patients after surgery

Variables	Conventional hip replacement (n = 56)	3D printing hip replacement (n = 51)	P-value
	(mean ± SD)	(mean ± SD)	
Harris score			
Before surgery	56.6 ± 4.7	57.7 ± 5.2	.250
After surgery	81.2 ± 2.8	93.3 ± 2.7	.001
Operative time (min)	63.7 ± 10.3	39.9 ± 10.3	.001
Bleeding (ml)	550.2 ± 11.2	525.3 ± 13.4	.001
Time to full weight-bearing (days)	3.1 ± 0.2	1.5 ± 0.2	.001
	N (%)	N (%)	
Infection			
Yes	3 (5.4 %)	1 (2 %)	.053
No	53 (94.6 %)	50 (98 %)	
Loosening			
Yes	2 (3.6 %)	1 (2 %)	.041
No	54 (96.4 %)	50 (98 %)	
Dislocation			
Yes	2 (3.6 %)	1 (2 %)	.018
No	54 (96.4 %)	50 (98 %)	

Table 4. Comparison of bilateral hip joint angles after hip replacement.

Angle	Conventional hip replacement (n = 56)	3D printing hip replacement (n = 51)	P-value
Contralateral side (degrees)	(mean ± SD)	(mean ± SD)	
Femoral anteversion angle	17.57 ± 2.80	13.06 ± 1.93	.001
Neck shaft angle	125.66 ± 14.25	123.85 ± 15.07	.525
Acetabular angle	13.41 ± 3.94	12.02 ± 3.40	.055
Sharp angle	4.29 ± 4.56	41.54 ± 4.11	.141

[18]. Subsequently, developmental anomalies such as concentric joint space narrowing, modified anatomy of the acetabulum its thick medial wall and shallow depth with poor bone quality, torsional deformities of the femur, contribute to the impairment of the functional hip motion and results in bony dysmorphism combined with the severe pain [9]. Patients with Crowe type III and IV developmental hip dysplasia present many challenges for surgeons because of their increased femoral anteversion, shortened femoral neck, narrow femoral canal, limb-length discrepancy and muscle contracture of the adductor longus; therefore surgeons need to carefully choose the right prosthesis, to achieve a high degree of deformity correction [6]. THA approaches in developmental hip dysplasia have been accepted widely as a reliable therapeutic intervention with good incomes [19].

Recently, 3D modeling after the MRI or CT scan has become more commonly used in preoperative planning as it helps surgeons to plan the operation to improve its success rate [20]. It has been reported that the successful deployment of a 3D hip modeling program used on 21 patients with severe hip deformity resulted in a shorter duration of the surgery and accurate implantation of the components [21]. Furthermore, Kim et al. [14] described preoperative planning using a pelvis model created using a 3D printing technique, and subsequently, the 3D printed implant of the model has been successfully used in the surgery. Others have later implemented such surgical programs providing customized components in joint replacement surgeries [9].

Inner Mongolia is a northern province in China, where hip TB and developmental hip dysplasia are prevalent. Patients with these diseases tend to have substantial variations in their hip anatomy. Hip replacements using conventional components are the "gold standard"; however, there are some culprits such aseptic and septic loosening in failed hip replacements [22]. A review of the literature summarizes the reasons for hip replacement failures as aseptic loosening of the prosthesis, osteolysis, and infection around the joints [23]. Taking this into account, in this study, we used the infection and loosening rates as a means to evaluate the postoperative period. Our study revealed that the infection and loosening rates were lower in those who received the 3D printed femoral component compared to those who received a conventional femoral component, which indicates the positioning of the prosthesis in the 3D group was satisfactory, in our study. Moreover, the time to full weight-bearing in the patients receiving custom 3D printed femoral components was shorter than for those receiving conventional femoral hip replacement components and the postoperative Harris scores were higher in the custom group. These results show that the 3D printed prostheses in our study were closer to patients' anatomy, provided better biomechanics, speeded up the recovery of patients after surgery and improved their quality of life. Moreover, our results revealed that there was a significant decrease in the femoral anteversion angle with a value of 13.06 $\pm$ 1.93 degrees (mean $\pm$ SD) in the custom group compared to the 17.57 $\pm$ 2.80 degrees for the conventional hip replacement patients ($p = .001$). It should be noted, however, that neck-shaft angle, and the acetabular angle between did not differ from the contralateral side.

However, our study has limitations. First, the research was limited by its small sample size, lower than we aimed. Surely, a larger sample size would have yielded more statistical power. Furthermore, this study has been conducted in one particular hospital in northern China. Therefore, future research should pursue a generalized study in multiple hospitals in various regions.

3D-printed models can assist preoperative planning and simulation of complex surgical or interventional procedures, serve as a useful tool for the education of medical students and patients, and improve doctor-patient communication in many medical areas [10].

The adoption of 3D printing technology for surgical applications is becoming mainstream and offers novel, creative opportunities for designing hip replacement prostheses. Today, the manufacturing of conventional and individualized hip replacement prostheses are limited to metal, ceramic and plastic. Research on other materials such as collagen, chondroitin sulfate, hyaluronic acid, and hydroxyapatite is still in the laboratory stages [24,25]. Nevertheless, the development of the new materials and technologies, tissue engineering as well as digital medicine, are of great importance, as they can be used with 3D printing technology [26].

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